9/24/12

Interim Report – Open Heart Surgery Standard Advisory Committee

Current status of the SAC is summarized with comments organized according to individual charges. We have just completed our sixth meeting. Two additional subcommittees were formed to help address specific questions relative to project delivery requirements and initiation volumes for new OHS programs.

Charge 1. Review and update, if necessary, the initiation and maintenance volume requirements given that OHS volumes are declining.

Dr. Frank Shannon headed a subcommittee that researched the initiation volume issue. He reported that there are currently 26 states that utilize the CON process with a fairly wide variation in initiation and maintenance volumes. His examples showed initiation volumes ranging from 150-350 cases per year with maintenance volumes ranging from 200-350 per year. In most states, the maintenance volume had to be attained by year 3. Initial threshold numbers generally have been influenced by the Inter-Society Commission for Heart Disease Resources that recommended an initiation volume of 200 cases per year in 1972. The second significant influence was the recommendation of the American College of Cardiology / American Heart Association Task Force that initiation volumes be in the range of 200-300 cases per year. This recommendation was made in 1991.

The most recently approved OHS programs have not been achieving the number of OHS cases projected by the formula in place prior to 2007-8. The formula was "readjusted" in 2007-8 by an update to the allocation weights, and the new formula has been used once to assess an application for a new OHS program. By

report, that program was denied an OHS CON due to a projected OHS volume of approximately 150 cases per year. In the view of the subcommittee, but in the absence of rigorous statistical analysis, the methodology seemed to be working appropriately to generate numbers that were in keeping with the performance of other recent programs. Therefore, they recommended no change to the current initiation volume of 300 OHS cases per year, and no change in the formula to project OHS cases save for the already mandated periodic updates of the allocation weights.

General discussions relative to maintenance numbers have highlighted the fact that 11 of the 33 OHS sites have not been meeting their maintenance thresholds. It has been noted frequently that there is no clearly demonstrable link between program numbers and quality of outcomes for CABG, suggesting that annual program OHS case number is less than robust as a measure of the performance of an OHS program. Nonetheless, there has been limited discussion relative to modifying these numbers.

Charge 2. Review project delivery requirements to assure quality, measurability, and affordability for both the provider and consumer.

A subcommittee chaired by Dr. Alonso Collar was formed to review the current project delivery requirements to assess the need for any substantive changes. They calculated that if all OHS cases performed in the state were evenly distributed among all of the surgeons in the state, each surgeon would do 79 OHS operations per year. Given that there is wide variation in number of cases performed at the institutional and surgeon level, many surgeons would not meet the 75 case per year requirement in spite of their ability to deliver quality performance consistently. Recognizing the overall decline in OHS cases throughout the state, and noting that earlier project delivery requirements accepted a 50 case per year minimum for surgeons as adequate, a

recommendation to reduce the current requirement to 50 cases per year was proposed and approved.

There were also two observations relative to the project delivery requirements. The first related to the 300 OHS cases per year maintenance number. That number was felt by several members to "lack validity" due to the fact that institutional case numbers have not been shown to relate to quality for CABG outcomes. Further, pediatric OHS procedures that are as complicated if not more complicated than adult cardiac procedures are required at a level of only 100 cases per year for institutions offering those services. The second observation was that guaranteed access for OHS suggests affordability for the consumer but doesn't address or define it specifically.

Recognizing that annual program OHS case number is not a surrogate for quality, discussion continued in earnest with regard to a possible quality metric by which OHS programs might be evaluated in the future. Initially, the Open Heart Coalition proposed a multi-component scorecard of sorts that could be used to assess quality. However, this was felt to be too cumbersome, and the thresholds for acceptable and unacceptable performance were controversial. The star rating and composite score generated by the Society of Thoracic Surgeons appealed to many as a more simplified approach to rolling multiple quality indicators into a single, simple, and statistically validated score. The Open Heart Coalition subsequently took this concept back to its members and returned with a proposal by which the star rating might be used to trigger corrective action by the MDCH. The committee received this proposal favorably, but has not yet reached consensus on the ideal implementation.

Charge 3. Review and update, if necessary, the methodologies to assure they accurately reflect community need for OHS services.

The discussion of need has centered primarily on the number of OHS cases performed at each institution. It was suggested that number of OHS cases reflects or defines the need in a particular area. If the number of OHS cases in an area is declining, then it has been concluded that so has the need and that the need is currently being met. The vast majority of OHS programs are operating well below their peak rates of 10-12 years ago, allowing them room/capability to scale up or down as needed to support their communities.

Charge 4. Propose standards for percutaneous insertion of heart valves.

No additional discussion of this topic.

Charge 5. Consider any necessary technical or other changes, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

There continues to be a sentiment among the SAC members that if we are able to reach a consensus on a specific quality metric, that it should be applied equally to all programs in the state and not just those failing to meet minimum maintenance numbers. It is understood by the SAC that it may not be possible to mandate this action within the CON process, yet the SAC seems to gravitate toward the ideal in this situation rather than the facile.

Respectfully submitted,

Timothy Sell, M.D.